K120014

Stago

MAR 1 4 2013

510(k) Summary

Submitter's Information

Diagnostica Stago, Inc.
Five Century Drive
Parsippany, New Jersey 07054

Phone Number: 973 631-1200
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Date Prepared: March 1, 2013

Contact Person:

Delphine Ysvelain

Regulatory Affairs Manager

Device Name: STA® - Coag Control (N + ABN) PLUS

Device Classification: Class II
Regulation Number: 21 CFR 864.5425
Panel: Hematology (81)
Product Code: GGN

Predicate Device: STA® - System Control N + P - K943518
Manufacturer: Diagnostica Stago
(Formerly known as American Bioproducts)

Device Intended Use:

The STA® - Coag Control (N +ABN) PLUS is a kit containing assayed normal and abnormal plasmas intended for the quality control of the following quantitative tests on STA-R® and STA Compact® analyzers: prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen, thrombin time (TT), and antithrombin (AT).

Device description:

The STA® - Coag Control (N + ABN) PLUS kit is a set of two control levels.

Each kit provides:

- 12 x 2-ml vials of Reagent 1 (STA® - Coag Control N PLUS), citrated normal human plasma, lyophilized.
- 12 x 2-ml vials of Reagent 2 (STA® - Coag Control ABN PLUS), citrated abnormal human plasma, lyophilized.

STA® - Coag Control (N + ABN) PLUS Reagents are used as controls for clotting assays (PT, APTT, fibrinogen, and TT) and chromogenic assays (AT) performed on analyzers of the STA® line.

Analyzers of the STA® line utilize the chronometric principle (viscosity based detection system) for clotting tests while the chromogenic assays are based on the photometric method (measurement of absorbance of monochromatic light).

Statement of technological characteristics of the device compared to predicate device:

STA® - Coag Control (N + ABN) PLUS is substantially equivalent to its predicate device, STA® - System Control N + P (K943518), based on similar intended use, technology and principles of operation, thus yielding no new questions in safety, effectiveness or technology.

Summary Performance Characteristics

✓ *Precision*

Precision studies were performed according to the CLSI guideline EP5-A2. STA® - Coag Control N PLUS and ABN PLUS were tested for 20 days, 2 runs per day, in duplicate on STA-R® and STA Compact®.

The following results have been obtained

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• on STA-R®:	Repeatability CV (%)		Within-laboratory precision CV (%)	
	N PLUS	ABN PLUS	N PLUS	ABN PLUS
PT (in sec.) with STA® - Néoplastine® CI	0.9	0.6	1.1	2.0
PT (in sec.) with STA® - Neoplastine® CI Plus	0.9	0.5	1.1	1.9
APTT (in sec.) with STA® - C.K. Prest®	0.6	0.8	1.3	1.8
APTT (in sec.) with STA® - Cephascreen®	0.7	0.7	2.1	1.9
APTT (in sec.) with STA® - PTT A	0.9	1.0	2.6	1.9
Fibrinogen (in g/l) with STA® - Fibrinogen	2.4	4.2	3.5	5.5
TT (in sec.) with STA® - Thrombin	2.4	1.9	2.8	3.4
AT (in %) with STA® - Stachrom® AT III	1.9	3.9	3.6	5.3

• on STA Compact®:	Repeatability CV (%)		Within-laboratory precision CV (%)	
	N PLUS	ABN PLUS	N PLUS	ABN PLUS
PT (in sec.) with STA® - Néoplastine® CI	1.4	0.7	2.3	2.1
PT (in sec.) with STA® - Néoplastine® CI Plus	1.5	1.1	2.3	2.0
APTT (in sec.) with STA® - C.K. Prest®	1.2	1.0	2.3	2.1
APTT (in sec.) with STA® - Cephascreen®	1.6	1.1	2.3	1.8
APTT (in sec.) with STA® - PTT A	1.3	0.8	3.1	1.7
Fibrinogen (in g/l) with STA® - Fibrinogen	4.1	2.0	5.2	3.8
TT (in sec.) with STA® - Thrombin	1.3	1.4	3.5	5.4
AT (in %) with STA® - Stachrom® AT III	2.7	2.8	4.6	4.4

Substantial Equivalence Comparison Table:

Similarities		
Item	**Subject Device** **STA® - Coag Control (N + ABN) PLUS**	**Predicate Device** **STA® - System Control N + P** K943518
Intended Use	For the quality control of the following coagulation assays: prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen, thrombin time (TT) and antithrombin (AT) in the normal and abnormal ranges.	Same, except: - additional analytes claimed for the intended use in the normal and abnormal ranges - the thrombin time is determined in the normal range only.
Number of levels per set	2 (one normal and one abnormal)	Same
Matrix	Citrated Human plasma	Same
Form	Lyophilized	Same
Reagent preparation	Reconstitution with distilled water	Same

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Similarities		
Item	**Subject Device** **STA® - Coag Control (N + ABN) PLUS**	**Predicate Device** **STA® - System Control N + P** K943518
Principle of operation	Used as controls for clotting assays (PT, APTT, fibrinogen, and TT) and chromogenic assays (AT)	Same
Analyzers	STA-R® STA Compact®	Same as well as STA Satellite®
Shelf-life	24 months at 2-8 °C in intact vials	Same
Differences		
Item	**Subject Device** **STA® - Coag Control (N + ABN) PLUS**	**Predicate Device** **STA® - System Control N + P** K943518
Reconstituted Reagent stability	24 hours on-board analyzers	8 hours on-board analyzers

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 14, 2013

Diagnostica Stago, Inc.
c/o Ms. Delphine Ysvelain
Regulatory Affairs Associate
5 Century Drive
Parsippany, New Jersey 07054

Re: k120014
Trade/Device Name: STA® - Coag Control (N + ABN) PLUS
Regulation Number: 21 CFR § 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: GGN
Dated: March 6, 2013
Received: March 7, 2013

Dear Ms. Ysvelain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

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10.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K120014

Device Name: STA® - Coag Control (N + ABN) PLUS

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Leonthena R. Carrington -S

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120014